f=Potency of clindamycin working standard in milligrams of clindamycin per milligram;
W_a=Average capsule fill weight in milligrams,

(2) *Moisture.* Proceed as directed in §436.201 of this chapter.

[39 FR 19161, May 30, 1974, as amended at 50 FR 19921, May 13, 1985; 54 FR 41824, Oct. 12, 1989; 54 FR 43384, Oct. 24, 1989]

§453.121 Clindamycin palmitate hydrochloride oral dosage forms.

§453.121a Clindamycin palmitate hydrochloride for oral suspension.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Clindamycin palmitate hydrochloride for oral suspension is composed of clindamycin palmitate hydrochloride with one or more suitable and harmless diluents, buffer substances, colorings, and flavorings. When reconstituted as directed in the labeling, using the accompanying diluent when provided, each milliliter contains clindamycin palmitate hydrochloride equivalent to 15 milligrams of clindamycin. Its clindamycin content is satisfactory if it is not less than 90 percent and not more than 120 percent of the amount of clindamycin that it is represented to contain. The moisture content is not more than 3.0 percent. When reconstituted as directed in the labeling, its pH is not less than 3.0 and not more than 5.0. The clindamycin palmitate hydrochloride used conforms to the standards prescribed by §453.21(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of §432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of §431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The clindamycin palmitate hydrochloride used in making the batch for clindamycin content, moisture, pH, and identity.

(*b*) The batch for clindamycin content, moisture, and pH.

(ii) Samples required:

(*a*) The clindamycin palmitate hydrochloride used in making the batch: 10 packages, nine containing not less than 300 milligrams, and one containing not less than 2 grams.

(*b*) The batch: A minimum of six immediate containers.

(b) *Tests and methods of assay*—(1) *Clindamycin content.* Proceed as directed in §436.303 of this chapter, except:

(i) *Preparation of clindamycin palmitate hydrochloride sample and working standard solutions.* Accurately weigh about 130 milligrams of the clindamycin palmitate hydrochloride working standard and transfer to a 25-milliliter volumetric flask. Add 5 milliliters of distilled water. Reconstitute the clindamycin palmitate hydrochloride for oral suspension as directed in the labeling, using the accompanying diluent when provided, and transfer exactly 5.0 milliliters to a 25-milliliter volumetric flask. Add exactly 5.0 milliliters of internal standard and 1 milliliter of 30 percent sodium carbonate to each flask. Shake both flasks mechanically for 5 minutes. Transfer the contents of each flask to separate 15-milliliter glass-stoppered centrifuge tubes and centrifuge. Remove the top aqueous layer by suction and transfer exactly 1.0 milliliter of the chloroform layer to separate glass-stoppered, conical, 15-milliliter centrifuge tubes. Add 1 milliliter of pyridine and 0.5 milliliter of acetic anhydride. Agitate the tubes to insure complete mixing of the liquids. Proceed as directed in §436.303(e) of this chapter.

(ii) Calculations: Calculate the clindamycin content as follows:

$$\text{Milligrams of clindamycin per milliliter} = \frac{R_u \times W_s \times f}{R_s \times V}$$

where:
R_u=Area of the sample peak (at a retention time equal to that observed for the clindamycin palmitate hydrochloride standard)/Area of internal standard peak;
R_s=Area of the clindamycin palmitate hydrochloride standard peak/Area of internal standard peak;
W_s=Weight of the clindamycin palmitate hydrochloride working standard in milligrams;
V=Volume of reconstituted sample in milliliters;
f=Milligrams of clindamycin activity per milligram of clindamycin palmitate hydrochloride working standard.